II. Remarks

Claims 1-38 are rejected and pending. Although not required, a listing of the pending claims has been provided for the Examiner's convenience. With the remarks provided below, Applicants respectfully request reconsideration and a withdrawal of all rejections.

Responsive to the rejections of claims 1, 4, 8-11, and 13-15 under 35 U.S.C. § 102(b), *Engelson et al.* fail to teach each and every element as set forth in the invention as claimed in the present application. Claim 1 recites a medical device comprising "a unitarily and continuously formed portion (108) having a varying durometer." In the present application, the applicants define "unitarily and continuously" to mean more than merely securing pieces of different durometer to one another. "Instead, the unitary, continuous material employed in the present invention is a single piece, even though the chemical composition or structure of the material may be somewhat modified along the length of the piece (due to selective cross-linking). This stands in direct contrast to prior devices in which discrete parts having different durometers are secured to one another." Specification, page 19, lines 5-11.

Contrarily, *Engelson et al.* teach a medical device that is non-unitary and non-continuous. More specifically, *Engelson et al.* teach a catheter having three different segments: a proximal segment (122), a transition section (124), and a distal segment (120). Column 5, lines 30-40; column 7, lines 3-10; see also Figure 1. *Engelson et al.* further teach that the segments 120, 122, and 124 may be made of differing materials.

Responsive to the rejections of claims 1-6, 8-11 and 13-18 under 35 U.S.C. § 102(b), *Preissman et al.* fail to teach each and every element as set forth in the invention as claimed in the present application. As mentioned above, claim 1 recites a medical device comprising "a unitarily and continuously formed portion (108) having a varying durometer." As stated above, the Applicants define "unitarily and continuously" on page 19 of the specification of the present application.

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Contrarily, *Preissman et al.* fail to teach a medical device that is unitarily and continuously formed. Rather, *Preissman et al.* teach a high torque balloon catheter having a catheter body with three distinct regions: a shaft region, a transition region and a distal region. *Preissman et al.*, column 6, lines 25-46. The regions have differing flexibility based on a selected length of different layers of materials. See column 2, lines 53-59. For example, the catheter body includes an inner tubular member, a braided reinforcement layer, and a soft outer layer. The shaft region of the catheter body comprises all three layers: the inner tubular member, the braided reinforcement layer and the soft outer layer. The shaft region has the least flexibility, but has excellent torque transmission and hoop strength characteristics. See column 3, lines 17-21. On the other hand, the distal region only includes the soft outer layer thereby having the greatest flexibility, but with minimum torque ability and hoop strength. Clearly, the catheter body of the balloon catheter taught in *Preissman et al.* fails to comprise a unitary and continuously formed portion as recited in independent claim 1 of the present application.

Claims 2-35 are dependent on claims which depend generally from claim 1. Thus, claims 2-35 are allowable for the reasons provided above.

Responsive to the rejection of claim 7 under 35 U.S.C. § 103(a) as being unpatentable over *Preissman et al.*, *Preissman et al.* do not teach or suggest all the elements of dependent claim 7. Claim 7 is a dependent claim which depends generally from claim 1, the elements of which are not taught or suggested by *Preissman et al.* In addition, there is no suggestion or motivation to provide an anchor structure comprising a malecot, a pigtail, or a loop as recited in dependent claim 7.

Responsive to the rejections of claims 19-25 and 28-35 under 35 U.S.C. § 103(a) as being unpatentable over *Engelson et al.* or *Preissman et al.*, neither *Engelson et al.* nor *Preissman et al.* teaches or suggests all the elements of claims 19-25 and 28-35. As stated above, neither *Engelson et al.* nor *Preissman et al.* teaches or suggests all the elements of independent claim 1 from which claims 19-25 and 28-35 depend. In addition, there is no motivation in either *Engelson et al.* or

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Preissman et al. to combine them to result in all the limitations and specific materials recited in claims 19-25 and 28-35.

Moreover, *Engelson et al.* fail to teach all the limitations set forth in dependent claim 19. Dependent claim 19 recites that "the unitarily and continuously formed portion comprises an irradiation cross-linkable mixture of a polyamide elastomer and at least one additional cross-linking reactant." *Engelson et al.*, however, teach that the substrate of the polymeric catheter may merely be sprayed, dipped, dried, or irradiated to produce a polymerized and cross-linked polymeric skin which coats the catheter substrate. See *Engelson et al.*, column 4, lines 17-20 and 60-67. Thus, the catheter taught by *Engelson et al.* is not "unitary and continuous" as claimed and defined in the present application. Moreover, the catheter taught by *Engelson et al.* is not "an irradiation cross-linkable mixture." Clearly, *Engelson et al.* do not teach all the limitations of claim 19.

Responsive to the rejections of claims 26-27 under 35 U.S.C. § 103(a) as being unpatentable over *Preissman et al., Preissman et al.* fail to teach or suggest all the elements of claims 26-27. *Preissman et al.* do not teach or suggest all the elements of independent claim 1 from which claims 26-27 generally depend. In addition, there is no motivation in *Preissman et al.* to modify its device to result in all the limitations and materials recited in claims 26-27.

Responsive to the rejections of claims 36-38 under 35 U.S.C. § 103(a) as being unpatentable over *Preissman et al., Preissman et al.* fail to teach or suggest all the elements of claims 36-38. Independent claims 36-38 recite a medical device comprising "a unitarily and continuously formed portion (108) having a varying durometer." *Preissman et al.* fail to teach or suggest a medical device that is unitarily and continuously formed as claimed in claims 36-38. *Preissman et al.*, however, teach a high torque balloon catheter having a catheter body with three clearly different distinct regions: a shaft region, a transition region and a distal region. In addition, there is no motivation in *Preissman et al.* to modify its device to result in all the limitations and materials recited in claims 26-27.

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Therefore, claims 1-38 are in a condition for allowance and such action is earnestly solicited.

Respectfully submitted,

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Date

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